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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,827

Applicant(s)

ERIKSON ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 12-51 is/are pending in the application.
- 4a) Of the above claim(s) 26-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12-25, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

1. Upon reconsidering and careful review, the finality of the last office action is withdrawn herein and the case is reopened for prosecution.

Response to Arguments

2. Amendment filed on May 18, 2004 is acknowledged.

3. Applicants' response and amendments have been entered and are fully considered.

4. With regard to the rejection under 35 USC 102(b) in the previous office action, Applicants' arguments have been fully considered and found not persuasive. Applicants argue that the prior art McGavin et al. disclose a theoretical model for quadruplex nucleic acid sequences based on the Watson-Crick tetrads and does not teach or suggest the structures with real nucleic acids and thus McGavin et al. reference is a non-enabling art. These arguments are fully considered and found not persuasive because in previous office action Applicants submitted the same reference to show that the Watson-Crick base pairing is enabled by the McGavin reference. Contradictory to this, presently, Applicants argue that the prior art is non-enabling prior art. Examiner notes that one of ordinary skill in the art would rely on the McGavin reference for the structure as claimed in the instant invention because Applicants did not show any crystallographic data to show how the instantly claimed structure is formed with Watson-Crick base pairing involving more than two strands. Applicants' reference to a case law is fully considered however it is noted in MPEP 2121.04 "Pictures and drawings may be sufficiently enabling to put the public in the possession of the article pictured. Therefore, such an enabling picture may be used to reject claims to the article. However, the picture must show all the claimed structural features and how they are put together. Jockmus v. Leviton, 28 F.2d 812 (2d Cir. 1928). See also MPEP § 2125

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for a discussion of drawings as prior art. Thus the computer graphic structure disclosed by McGavin et al. is considered as enabling art. And hence the rejection for claims 1, 3-4, 7-9, 13-14, 19 is maintained herein.

Further, after careful review of the McGavin et al. reference, and the limitations in the amended claims, it is noted that the incorporation of limitations in the amended claims, are inherent in the teachings of McGavin et al. because McGavin et al. teaches that the major groove of the first strand and said second strand is placed in a major groove of said third and fourth strand, which inherently teaches that each nucleobase in the first and second strand binds to the nucleobases of third and fourth strands. To address the new limitations in the instant claims the rejection is rewritten below.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 6-10, 12-14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by McGavin et al. (J. Mol. Graphics, Vol. 7, pages 218-232, 1989).

McGavin et al. teach a multiplex structure of claim 1, using computer graphics wherein McGavin et al. disclose a multiplex structure comprising a first, a second, a third and a fourth sequence of nucleobases wherein four strands interact specifically with each other forming a multiplex structure solely through Watson-Crick pairing (see page 226, column 1, paragraphs 2-

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4) in which Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact, which indicates or teaches that each nucleobase in each strand of multiplex structure are bound to another nucleobase of another strand in the multiplex (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3).

With regard to claim 1, McGavin et al. teach that the multiplex structure comprises an artificial or synthetic quadruplex (see page 228, column 1, paragraphs 2-4);

With regard to claims 3-4, 6, McGavin et al. teach that the multiplex structure comprises a nucleic acid (DNA and RNA) (see page 225, column 2, paragraph 3);

With regard to claims 7, 9, McGavin et al. teach the multiplex structure any one strand alternates between two strands in anti-parallel orientation (see page 220, color plate 3a and 3b, page 228, column 2, paragraphs 3-8);

With regard to claims 8, 10, 12, McGavin et al. teach Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact indicating major groove of first-second strand duplex is placed in the major groove of third-fourth strand duplex, indicating no strand is contiguous with another strand (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3);

With regard to claim 13-14, McGavin et al. teach that the multiplex structure is substantially free of Hoogsteen bonding and free of G-G quartets (see page 226, column 1, paragraph 2, column 2, paragraph 2);

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With regard to claim 19, McGavin et al. teach that the multiplex structure is free of a solid support (see page 226, column 2, paragraphs 3-5).

Thus the disclosure of McGavin et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 15-18, 20-25, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable McGavin et al. (J. Mol. Graphics, Vol. 7, pages 218-232, 1989) in view of George Jr. (USPN. 5,451,502).

McGavin et al. teach a multiplex structure of claim 1, using computer graphics wherein McGavin et al. disclose a multiplex structure comprising a first, a second, a third and a fourth sequence of nucleobases wherein four strands interact specifically with each other forming a multiplex structure solely through Watson-Crick pairing (see page 226, column 1, paragraphs 2-

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4) in which Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact, which indicates or teaches that each nucleobase in each strand of multiplex structure are bound to another nucleobase of another strand in the multiplex (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3).

McGavin et al. teach that the multiplex structure comprises a nucleic acid (DNA and RNA) (see page 225, column 2, paragraph 3); the multiplex structure any one strand alternates between two strands in anti-parallel orientation (see page 220, color plate 3a and 3b, page 228, column 2, paragraphs 3-8); Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact indicating major groove of first-second strand duplex is placed in the major groove of third-fourth strand duplex (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3). However, McGavin et al. did not specifically teach a nucleic acid analogue (a therapeutic, prophylactic or diagnostic agent), length of the strands in the multiplex structure, use of haplotype genomic DNA or PCR products, a solid support.

George Jr. teaches method for creating a nucleic acid multiplex (see column 3, lines 49-67, column 4, lines 1-35) wherein the method comprises

(a) creating a mixture comprising water (buffer), a Watson-Crick duplex (double-stranded nucleic acid) (see column 3, lines 49-61, column 4, lines 1-16), a number of single-stranded mixed base sequence molecules (probe or oligonucleotide containing at least a nucleobase sequence) (see column 3, lines 49-58), at least one accelerator agent (label) and

(b) incubating the reaction mixture to form said multiplex (see column 4, lines 10-16).

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George Jr. also teaches that the probe strand comprises up to 100 nucleotide bases and target contains complementary bases to said probe strand (see column 6, lines 1-24, column 9, lines 11-23); a fluorephore label, fluorescence, chemiluminescence label comprising rodhamine and fluorescein (see column 7, lines 1-19); a fluorephore label with detectable marker using an atom, an inorganic radical (comprise monovalent cation), heavy metal (transition metals) (divalent or valency grater than 1), ligands like biotin, receptors (analogues) creating charged strands (see column 6, lines 25-46); Genomic DNA from any source, double-stranded cDNA, or a mixture of nucleic acids (see column 5, lines 47-60); the multiplex structure is immobilized on a solid support (see column 7, lines 35-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of forming or creating a multiplex as taught by McGavin et al. with the detectable label or analogue as taught by George Jr. in order to achieve a sensitive and enhanced diagnostic agent because George Jr. taught that the sensitivity and enhanced signal of nucleic acid complex and its significance in providing a highly sensitive nucleic acid recycling or probe amplification in diagnostic systems. An ordinary artisan would have recognized the expected benefits of sensitivity of the multiplex structures and would have motivated to add the limitations taught by George Jr. to enhance the sensitivity and diagnostic potential of the multiplex structure.

Conclusion


No claims are allowable.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
June 3, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER
